

CIRM's Alpha Stem Cell Clinics Given High Profile Role in Clinical Trials Network

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Oakland, CA – There are a growing number of predatory clinics in California and around the US, offering unproven stem cell therapies. For patients seeking a legitimate therapy it can often be hard finding a reliable clinic, one offering treatments based on the rigorous science required in a clinical trial sanctioned by the US Food and Drug Administration (FDA). That's one of the reasons why the California Institute for Regenerative Medicine (CIRM) created the CIRM Alpha Stem Cell Clinic Network and we are delighted the clinics have now been chosen as a Core program of the American Society of Hematology (ASH) Sickle Cell Disease (SCD) Collaborative Trials Network.

The Alpha Clinics are a network of top California medical centers that specialize in delivering stem cell clinical trials to patients. It consists of five leading medical centers throughout California: City of Hope, University of California (UC) San Diego, UC Irvine & UC Los Angeles, UC Davis and UC San Francisco.

The mission of the ASH Research Collaborative SCD Clinical Trials Network is to improve outcomes for individuals with Sickle Cell Disease by promoting innovation in therapy development and clinical trial research.

Like CIRM, the ASH Clinical Trials Network is a member of the National Heart, Lung and Blood Institute's Cure Sickle Cell Initiative. This is a collaborative partnership to accelerate the development of genetic therapies to cure SCD within five to ten years.

"The key to finding a cure for this crippling disease, and finding it quickly, is to work together", says Maria T. Millan, MD, President & CEO of CIRM. "That's why we are delighted to be chosen as a core program for the ASH Sickle Cell Disease Clinical Trials Network. This partnership means we can share data and information about best practices to help us improve the quality of the research being done and the clinical care we can offer patients. We already have 23 clinical stage therapies in cell and gene therapy, including two clinical trials targeting SCD, so we feel we have a lot to bring to the partnership in terms of experience and expertise."

Sickle Cell disease is a life-threatening blood disorder that affects 100,000 people, mostly African Americans, in the US. It is caused by a single genetic mutation that results in the production of "sickle" shaped red blood cells that can block blood vessels causing intense pain, recurrent hospitalization, multi-organ damage and strokes.

According to Mark Walters, MD, Director of UCSF Benioff Children's Hospital Oakland's Blood and Marrow Transplantation program, the currently available drugs treat the symptoms of sickle cell disease but are not a cure

"We hear a lot about the moonshot for curing cancer, but a moonshot for curing sickle cell disease should also be possible. Sickle cell disease was the first genetic disease that was discovered, and wouldn't it be great if it is also one of the first ones we can cure in everyone?"

It is hoped that creating this network of clinical trial sites across the US will better serve an historically underserved population.

- Establishing links and educational materials across these sites can increase patient engagement and recruitment
- Standardizing resources across the network can ensure efficiency and coordination
- Improving the training of clinical research staff can promote patient safety and trust and increase research quality

The CIRM Alpha Clinics Network has a proven track record of creating a faster, more streamlined approach in running clinical trials. It has developed the tools and systems to simultaneously launch clinical trials at multiple sites; created model non-disclosure agreements to make it easier for clinical trial sponsors to sign up; created a system to enable one Institutional Review Board (IRB) to approve a trial to be carried out at multiple sites rather than requiring each site to have its own IRB approval; developed best practices to quickly share experience and expertise across the network; and set up a database of over 20 million Californians to improve patient recruitment.

An Executive Summary prepared for the Western States Sickle Cell Disease Clinical Trials Network said: "the ASCC provides a

formidable clinical trial unit uniquely qualified to deliver the next generation of cell and gene therapy products for SCD."

About CIRM

At CIRM, we never forget that we were created by the people of California to accelerate stem cell treatments to patients with unmet medical needs, and act with a sense of urgency to succeed in that mission.

To meet this challenge, our team of highly trained and experienced professionals actively partners with both academia and industry in a hands-on, entrepreneurial environment to fast track the development of today's most promising stem cell technologies.

With \$3 billion in funding and approximately 300 active stem cell programs in our portfolio, CIRM is the world's largest institution dedicated to helping people by bringing the future of cellular medicine closer to reality.

For more information go to www.cirm.ca.gov

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